Sun Pharmaceuticals – Recall of Riomet ER™ (metformin)

- On September 23, 2020, Sun Pharmaceuticals announced a voluntary, consumer-level recall of one lot of Riomet ER (metformin) extended release oral suspension due to the level of N-Nitrosodimethylamine (NDMA), which has been found to be above the allowable Acceptable Daily Intake (ADI) limit established by the FDA.

- NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Product Description	NDC#	Lot # (Expiration Date)
Riomet ER (metformin hydrochloride for extended-release oral suspension), 500 mg per 5 mL	10631-019-17	AB06381 (10/2021)

- Riomet ER is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients ≥ 10 years of age with type 2 diabetes mellitus.

- Patients taking Riomet ER are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment.

- According to the FDA, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professionals. See here for more information about metformin products and NDMA contamination.

- To date, Sun Pharma has not received any reports of adverse events related to this recall.

- Patients who have the recalled Riomet ER should contact their physician or health care provider if they have experienced any problems that may be related to using the recalled Riomet ER.

- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.

- Contact Sun Pharma by phone at 1-800-818-4555 or by email at **drug.safetyUSA@sunpharma.com** for further information regarding this recall.